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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
077739,014	07/31/91	YAMAMOTO	24070-237-37

BARND, D EXAMINER

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ART UNIT	PAPER NUMBER
1813	8

DATE MAILED:

10/19/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined. ☒ Responsive to communication filed on 7-24-92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-10 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 11-13 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-10 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for _____

SN 07/739,014
Art Unit 1813

15. Applicant's cancellation of claims 11-13 in Paper No. 7 is acknowledged. Claims 1-10 are pending.

16. The text of those sections of 35 U.S. Code not included in this office action can be found in the prior office action.

17. The prior provisional rejection of claims 1-10 under 35 U.S.C 101 as claiming the same invention as that of claims 3-11 of copending application Serial No. 07/726,061 is withdrawn in view of Applicant's arguments and in view of the following new ground of rejection.

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-6 and 8-11 of copending application Serial No. 07/726,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use the FIV-infected cell line FL-4 or FL-6, or virus produced by such an FIV-infected cell line, as disclosed in application Serial No. 07/726,061 (and also disclosed in the instant application) as an immunogen in the vaccine claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or

patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

19. The prior rejection of claims 1-10 under 35 U.S.C. 101 based upon lack of utility is withdrawn in part and maintained in part.

The declaration under 37 C.F.R. § 1.132 filed 7-24-92 is sufficient to overcome the rejection of claims 1, 2, 4-8 and 10 based upon lack of utility.

The declaration under 37 C.F.R. § 1.132 filed 7-24-92 is insufficient to overcome the rejection of claims 3 and 9 based upon lack of utility as set forth in the last Office action because no evidence has been provided that a vaccine comprising attenuated FIV elicits protection against FIV infection. For example, it is unclear that the modifications of FIV which lead to attenuation of the virus will not also adversely affect the immunogenicity of the virus.

20. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are indefinite in their use of the phrase "a vaccine...capable of eliciting an immune response" and/or the phrase "cell line which expressed FIV antigens" because no positive statement of function (i.e. elicitation of an immune response, expression of FIV antigens) is made. Amendment of the claims to recite "a vaccine...which elicits an immune response" and/or the phrase "cell line which expresses FIV antigens" is suggested.

21. The prior rejection of claims 1-10 under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure is withdrawn in part and maintained in part. The rejection is withdrawn with respect to claims 1, 2, 4-8 and 10 because the utility of the invention has been demonstrated as set forth

supra. The rejection is maintained with respect to claims 3 and 9 because the utility of the invention has not demonstrated as set forth supra.

22. Claims 1, 2, 4-8 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a vaccine protective against FIV-Petaluma and FIV-Dixon, wherein the immunogen is inactivated whole FIV-Petaluma or an inactivated cell line which expresses antigens of such an FIV strain. See M.P.E.P. §§ 706.03(n) and 706.03(z). The disclosure is not enabling for the production and use of a vaccine protective against other strains of FIV (i.e. Maryland and Japanese strains of FIV which differ from FIV-Petaluma by 21-22% in outer envelope amino acid sequences, as stated by Yamamoto et al. in the manuscript submitted by Applicant), or which comprises FIV immunogens other than inactivated FIV-Petaluma-infected cell lines or inactivated, whole FIV-Petaluma (i.e. a vaccine comprising attenuated FIV, vaccines comprising individual FIV proteins or peptides).

23. The prior rejection of claims 4 and 10 under 35 U.S.C. 102(a) as being anticipated by Jarrett et al. is withdrawn. The declaration under 37 C.F.R. § 1.132 filed 7-24-92 is sufficient to overcome the rejection of claims 4 and 10 based upon the Jarrett et al. reference.

24. The prior provisional rejection of claims 1-10 as being anticipated by copending application Serial No. 07/726,061 is withdrawn. The declaration filed on 7-24-92 under 37 C.F.R. § 1.131 is sufficient to overcome the copending application Serial No. 07/726,061 reference.

25. No claims are allowable.

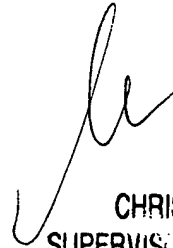
26. Papers relating to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to

Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna L. Barnd whose telephone number is (703) 308-3908. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

October 15, 1992

Donna L. Barnd, Ph.D.



CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180